UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/837,459	04/18/1997	MARIAN L. MCKEE	4995.0023	7600

7590 04/22/2003

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER
1300 I STREET NW
WASHINGTON, DC 200053315

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
08/837,459	McKee et al
Examiner	**Art Unit**
Portner	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jan 6, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *Apr 4, 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attachment.*

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attached response to remarks

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*

Claim(s) objected to: *none*

Claim(s) rejected: *60 and 66-96*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.

10. ☐ Other:

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER

1. The Amendment After Final submitted January 6, 2003, has not been entered as it raises new issues.

a. New claims 97-104 are proposed for entry, without canceling the equivalent number of claims now pending.

b. Claims 97-104 depend from independent claims 60, 73,76 and 96, either directly or indirectly and recite the phrase "is overexpressed recombinant intimin." The phrase "is overexpressed recombinant intimin" sets forth claim limitations have not previously been considered of record and therefore raises a new issue. These claim limitations have not prevously been considered on the record; no his-tagged recombinant intimin antigen is recited in the claims.

Response to Remarks

2. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

3. The rejection of claims 60, 66-71, 76-77, 80-81, 83, 85-88, 73-75, 84, 91-94, 78-79 and 82 under 35 U.S.C. 103(a) as being unpatentable over Childlow et al (US Pat. 4,141,970) in view of

Cravioto et al (1991) was traversed on the grounds that Childlow et al does not teach anti-intimin antibodies and purified intimin.

4. It is the position of the examiner that Applicant arguments are not commensurate in scope with the instantly claimed invention. The E.coli strain of Childrow et al comprised an enriched composition of purified E.coli O157 . The antibodies administered to the patient (infant piglet) prevented infection. Cravioto et al was cited to show that E.coli produces intimin. The composition of Childrow et al obviously comprised intimin due to an enriched composition of E.coli that produce intimin, in view of Cravioto et al that teaches E.coli produces intimin associated adhesin. The antibodies of Childrow et al were protective against infection thus prevented adhesence associated infection and establishment of disease. Childrow in view of Craviato obviate the instantly claimed invention.

5. The enriched intimin recited in the claims is not purified, only enriched. The composition of Childrow was enriched in cellular materials and Craviato et al shows that cellular material of E.coli contains intimin; the E.coli strain of Childrow was E.coli O157, in an enriched composition.

6. Childlow et al is directed to a method of providing a safer food supply, wherein the method of passively immunizing a patient is through active immunization, the administration of a composition that comprises E.coli 0157 (includes intimin) to of a milk producing mammal and

administering the generated antibodies to an offspring, during a modern stock-raising practice (see col. 1, lines 30-33).

Childlow et al teach that the sows, cows and ewes are to have the antigen composition administered to thereto, prior to or after breading (see col. 2, lines 16-23). Stock-raising practice includes, raising (stock raising, col. 1, line 32), breeding (pregnant mother animals, (see col. 2, line 6), and preparing (stock raising practice, improved health and weight gain (see col. 1, line 16 and 26) for food (modern stock-raising). Among the animals immunized are food source animals, specifically pigs, cows and sheep (see col. 2, line 29).

The rejection of the claims under 35 U.S.C. 103(a) Childlow et al in view of Cravioto et al is maintained for reasons of record.

7. The rejection of claims 60, 66-71, 76-77, 80-81, 83, 85-90, 73-75, 84, 91-95, 78-79, 82 and 96 under 35 U.S.C. 103(a) as being unpatentable over Dougan in view of Childlow et al (US Pat. 4,141,970), as previously applied to claims 60, 66-71,74, 76-77, 80-81, 83-90, is traversed through arguing the Dougan et al reference to only mention treatment with anti-intimin antibodies and asserts that the reference does not provide any "real motivation to use initimin or its antibodies therapeutically.

8. It is the position of the examiner that the rejection made of record was Dougan in view of Childlow et al; Dougan et al disclose anti-intimin antibodies that will bind to the region of intimin associated with biological activity and thus would interfere with and serve to treat E.coli infection.

The specific guidance provided by Dougan et al relates to "antibodies are therefore specific for the 280 amino acid domain of Int EPEC and will therefore be useful in the detection and/or treatment of EPEC infection (see col. 2, lines 24-43). Dougan clearly teaches that portion of intimin associated with binding activity (see col. 2, line 31) and antibodies that will bind specifically to this domain to block binding for treatment. The guidance provided by Dougan et al provides real motivation to immunize a host to obtain antibodies that will block infection/ treat infection (Dougan et al, col. 2, lines 40-44), caused by a human pathogen, wherein the antibodies are taught for the treatment of infection.

9. This position is based upon the definition of "enriched" provided in Applicant's specification at page 7, first paragraph : [to an enriched protein comprising intimin] ...[that induces antibodies that block wild-type binding activity]. Clearly the definition provides for the administration of an enriched intimin composition that is present in an inactivated whole cell, or whole cell lysate composition, that will induce an immune response to intimin. Childlow et al clearly teaches this composition (E.coli O157 (col. 3, line 11) and, col. 2, lines 66-67 and col. 3, lines 1-7), and Dougan et al teach a conserved, receptor associated portion of intimin for administration and induction of an immune response that will block binding and treat infection (see Dougan et al, '293, col. 2, lines 43-44). The claimed invention is obviated for reasons of record.